DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 16, 2014

CAROLINA LIQUID CHEMISTRIES CORP.
MELISSA THOMPSON
DIRECTOR, RA AND QA
575 N. PATTERSON AVE., SUITE 430
WINSTON-SALEM NC 27101

Re: K133519
Trade/Device Name: Carolina Liquid Chemistry CLC 6410 Chemistry Analyzer
Carolina Liquid Chemistry Glucose Reagent
Carolina Liquid Chemistry ISE Kit
Carolina Liquid Chemistry ISE Calibrator Kit
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose Test System
Regulatory Class: II
Product Code: CFR, JGS, CEM, CGZ, JIX, JJE
Dated: April 21, 2014
Received: April 28, 2014

Dear Mrs. Melissa Thompson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the

electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias -S

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k133519

Device Name
Carolina Liquid Chemistries CLC 6410 Chemistry Analyzer; Carolina Liquid Chemistries Glucose Reagent; Carolina Liquid Chemistries ISE Kit;Carolina Liquid Chemistries ISE Calibrator Kit

Indications for Use *(Describe)*
The Carolina Liquid Chemistries CLC 6410 chemistry analyzer is an automated clinical analyzer for in vitro diagnostic use only in clinical laboratories. It is intended to be used for a variety of assay methods. The analyzer provides in vitro quantitative determinations for glucose, sodium, potassium, and chloride in serum and plasma samples.

The Carolina Liquid Chemistries Glucose Reagent is for use with the Carolina Liquid Chemistries CLC 6410 Chemistry Analyzer for the measurement of glucose in serum and plasma. Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and of pancreatic islet cell carcinoma.

The Carolina Liquid Chemistries ISE Kit is intended to be used with the Carolina Liquid Chemistries CLC 6410 Chemistry Analyzer for measurement of sodium, potassium, and chloride in serum and plasma. The ISE Kit consists of ISE Buffer, internal reference solution, and reference solution. Sodium measurements are used in the diagnosis and treatment of diseases involving electrolyte imbalance. Potassium measurements monitor electrolyte balance and in the diagnosis and treatment of disease conditions characterized by low or high blood potassium levels. Chloride measurements are used for the diagnosis and treatment of electrolyte and metabolic disorders.

The Carolina Liquid Chemistries ISE Calibrator Kit consists of Calibrator 1, Calibrator 2, and Selectivity Check. It is used with the ISE Module on the Carolina Liquid Chemistries CLC 6410 Chemistry Analyzer for the calibration of the Sodium, Potassium and Chloride assays.

For in vitro diagnostic use only.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Yung W. Chan -S

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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